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Indian Standard

(Reaffirmed 1997)

BASIC REQUIREMENTS FOR ORTHOPAEDIC JOINT PROSTHESES

(ISO Title : Implants for Surgery — Orthopaedic Joint Prostheses — Basic Requirements)

National Foreword

This Indian Standard, which is identical with ISO 5839-1985 'Implants for surgery — Orthopaedic joint prostheses — Basic requirements' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of Orthopaedic Instruments and Accessories Sectional Committee and approval of the Consumer Products and Medical Instruments Division Council.

In the adopted standard, certain terminology and conventions are not identical with those used in Indian Standards; attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear, referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

Cross References

International Standard	*Corresponding Indian Standard*
ISO 5832 Implants for surgery — Metallic materials — Part 1: Wrought stainless steel	IS : 5347 (Part 2)-1986 Requirements for orthopaedic implants : Part 2 Wrought stainless steel
ISO 5832 Implants for surgery — Metallic materials — Part 2: Unalloyed titanium	IS : 5347 (Part 3)-1984 Requirements for orthopaedic implants : Part 3 Unalloyed titanium
ISO 5832 Implants for surgery — Metallic materials — Part 3: Wrought titanium 6-aluminium 4-vanadium alloy	IS : 5347 (Part 4)-1984 Requirements for orthopaedic implants: Part 4 Wrought titanium 6-aluminium 4-vanadium alloy
ISO 5832 Implants for surgery — Metallic materials — Part 4: Cobalt-chromium-molybdenum casting alloy	IS : 5347 (Part 5)-1984 Requirements for orthopaedic implants: Part 5 Cobalt chromium-molybdenum casting alloy
ISO 5832 Implants for surgery — Metallic materials — Part 5: Wrought cobalt chromium-tungsten-nickel alloy	IS : 5347 (Part 6)-1984 Requirements for orthopaedic implants: Part 6 Wrought cobalt-chromium-tungsten-nickel alloy
ISO 5832 Implants for surgery — Metallic materials — Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy	IS : 5347 (Part 7)-1984 Requirements for orthopaedic implants : Part 7 Wrought cobalt-nickel-chromium-molybdenum alloy
ISO 5832 Implants for surgery — Metallic materials — Part 7: Forgeable and cold formed cobalt-chromium-nickel molybdenum-iron alloy	IS : 5347 (Part 8)-1984 Requirements for orthopaedic implants : Part 8 Forgeable and cold-formed-cobalt-chromium-nickel-molybdenum-iron alloy
ISO 5833/1 Implants for surgery — Acrylic resin cements — Part 1: Orthopaedic applications	IS : 8641-1984 Acrylic resin cements for orthopaedic implants (*first revision*)
ISO 6474 Implants for surgery — Ceramic materials based on alumina	IS : 5347 (Part 9)-1984 Requirements for orthopaedic implants : Part 9 Ceramic materials based on aluminia

Orthopaedic Instruments and Accessories Sectional Committee, CPDC 24 [Ref : Doc : CPDC 24 (2088)]

Adopted 10 April 1987

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B U R E A U O F I N D I A N S T A N D A R D S
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The Orthopaedic Instruments and Accessories Sectional Committee has reviewed the provisions of the following ISO standards and has decided that these are acceptable for use in conjunction with this standard, till equivalent Indian Standards are available:

ISO. 5834 Implants for surgery — Ultrahigh molecular weight polyethylene; — Part 1: Powder form; Part 2 Moulded form

ISO 6018 Implants for surgery — General requirements for marking, packaging and labelling

ISO 7206/1 Implants for surgery — Partial and total hip joint prostheses — Part 1: Classification, designation of dimensions and requirements

ISO 7207/1 Implants for surgery — Partial and total knee joint prostheses — Part 1: Classification, definitions and designation of dimensions

0 Introduction

Orthopaedic joint prostheses are designed to transmit load and translate movement under high stress conditions. The task of preparing International Standards to cover all eventualities is complicated by the limited range of biologically suitable materials.

The purpose of this International Standard, and of other International Standards relating to joint prostheses, is to provide direction in the control of manufacture and standard specifications for the different components of prostheses.

The insertion and removal of a prosthesis for the purposes of trial fitting at the time of the operation can damage the prosthesis. For this reason, reduction tests should be carried out using a test prothesis, except in those cases where the prostheses are designed with protection for the bearing areas of the components. It is important, once implantation has been completed, that no components are used again after removal.

It is also necessary to take into account requirements for components of prostheses for partial and total replacement of particular joints. ISO 7206/1 and ISO 7207/1 deal, respectively, with partial and total hip joint prostheses and partial and total knee joint prostheses. Requirements for acrylic bone cement, commonly used in the implantation of joint prostheses, may be found in ISO 5833/1.

1 Scope and field of application

This International Standard specifies basic requirements for partial and total joint prostheses used in orthopaedic surgery, including those such as:

a) hip joint prostheses;

b) knee joint prostheses;

c) ankle joint prostheses;

d) shoulder joint prostheses;

e) elbow joint prostheses;

f) wrist joint prostheses;

g) finger joint prostheses;

h) toe joint prostheses.

Guidance on the use of joint prostheses is given in the annex.

2 References

ISO 5832, *Implants for surgery — Metallic materials —*

Part 1: Wrought stainless steel.

Part 2: Unalloyed titanium.

Part 3: Wrought titanium 6-aluminium 4-vanadium alloy.

Part 4: Cobalt-chromium-molybdenum casting alloy.

Part 5: Wrought cobalt-chromium-tungsten-nickel alloy.

Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy.

Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy.

ISO 5833/1, *Implants for surgery — Acrylic resin cements — Part 1: Orthopaedic applications.*

ISO 5834, *Implants for surgery — Ultra-high molecular weight polyethylene —*

Part 1: Powder form.

Part 2: Moulded forms.

ISO 6018, *Implants for surgery — General requirements for marking, packaging and labelling.* 1)

ISO 6474, *Implants for surgery — Ceramic materials based on alumina.*

ISO 7206/1, *Implants for surgery — Partial and total hip joint prostheses — Part 1: Classification, designation of dimensions and requirements.*

ISO 7207/1, *Implants for surgery — Partial and total knee joint prostheses — Part 1: Classification, definitions and designation of dimensions.*

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1) At present at the stage of draft.

3 Materials

NOTE — All components should be manufactured using recognized methods of quality control, for example those used in the production of aerospace components.

3.1 Metals

Metal components for joint prostheses shall be made of one or more of the following materials:

- wrought stainless steel of composition B, in accordance with ISO 5832/1 (see clause 5);
- unalloyed titanium, in accordance with ISO 5832/2;
- wrought titanium 6-aluminium 4-vanadium alloy, in accordance with ISO 5832/3;
- cobalt-chromium-molybdenum casting alloy, in accordance with ISO 5832/4;
- wrought cobalt-chromium-tungsten-nickel alloy, in accordance with ISO 5832/5;
- wrought cobalt-nickel-chromium-molybdenum alloy, in accordance with ISO 5832/6;
- forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy, in accordance with ISO 5832/7.

3.2 Plastics

Components made of ultra-high molecular weight polyethylene shall be made of material complying with the requirements of ISO 5834.

NOTES

1 Reference may be made to ISO 5833/1 for requirements for acrylic resin cements.

2 Components made of ultra-high molecular weight polyethylene should be stabilized, and the methods of processing and storing should maintain the dimensional stability of the component. Local heating should be avoided. Stress-relief annealing of semi-finished products may be required to ensure dimensional stability and freedom from distortion in the finished product. Details of suitable conditions should be obtained from the manufacturer of the polymer. The manufacturer of the component should keep records of the stabilization processes used.

3.3 Ceramics

Components made of alumina ceramic materials shall be of material complying with the requirements of ISO 6474.

4 Sterility

Prostheses and components shall, according to the requirements of the purchaser, be supplied either sterile or unsterile.

5 Design

Stainless steel shall not be used in combination with any other metal or alloy.

Stainless steel, unalloyed titanium and titanium alloys shall not form the contiguous bearing surfaces of joint prostheses.

NOTE — The following combinations have been found to be satisfactory:

a) Stainless steel/polyethylene;

b) Cobalt-based alloys/polyethylene;

c) Unalloyed titanium/polyethylene;

d) Titanium alloy/polyethylene;

e) Alumina/polyethylene;

f) Alumina/alumina.

6 Finish

6.1 Metals

6.1.1 General

The surfaces of metallic components, when examined with the naked eye (corrected if necessary), shall be free of imperfections such as scale, toolmarks, nicks, scratches, cracks, cavities, burrs and other defects that would impair the serviceability of the implant.

The surfaces, when examined with the naked eye (corrected if necessary), shall be free of embedded or deposited finishing materials or other contaminants. Components shall be cleaned, degreased, rinsed and dried. All polishing operations shall be performed using an iron-free medium.

6.1.2 Bearing surfaces

Bearing surfaces shall be polished to a mirror finish.

6.1.3 Non-bearing surfaces

Non-bearing surfaces intended to be in contact with soft tissues shall have either a polished or a satin finish.

6.1.4 Surface treatment

All surfaces shall be rendered passive by a process suitable for the metal concerned.

6.2 Plastics materials

The bearing surfaces of components made of plastics materials shall, in the as-delivered condition, be free from particulate contamination when examined with the naked eye (corrected if necessary). At no stage shall the bearing surfaces be prepared by a method employing an abrasive or polishing compound.

7 Sterilization of plastics components

7.1 General

Sterilization of components made of plastics materials shall be carried out by a verified method.

NOTE — The efficacy of the sterilizing process should be verified in a manner appropriate to the requirements of the relevant national authority.

7.2 Sterilization by irradiation

If methods of sterilization using ionizing radiation are used, no part of the component shall receive more than 3,5 Mrad during one sterilization. The dose shall be applied so as to maintain the functional geometry of the component. No component shall be sterilized by the manufacturer more than twice. The packaging materials of all components which are to be re-sterilized shall be discarded and the component re-packaged prior to sterilization. The absorbed minimum dose, the total cumulative dose and the number of times the component has been sterilized shall be stated on the package.

NOTE — Many national authorities require a minimum dose of 2,5 Mrad, to be applied during sterilization by means of ionizing radiation.

8 Packaging

Joint prostheses shall be packaged in accordance with the requirements of ISO 6018. Bearing surfaces shall be covered to protect the surfaces from damage. The protection shall comprise a material which leaves no debris or deposit on the surface of the prosthesis, nor induces chemical attack on the prosthesis under normal sterilization conditions.

NOTE — The protection during sterilization of bearing surfaces of unsterile components will form the subject of a future Technical Report.

9 Marking

9.1 Marking of components

Major components of joint prostheses shall be indelibly marked in accordance with the requirements of ISO 6018. All marking shall be located in a region of low stress and shall be performed in such a manner that the mechanical performance and corrosion resistance of the prosthesis are not significantly impaired.

9.1.1 Marking of metal components

In addition to the requirements of 9.1, an identifying mark shall be applied to each component of the joint prosthesis, if physically possible.

9.1.2 Marking of plastics components

Each component made of plastics material shall, if possible, be marked so as to identify the batch of material from which the component is made and for which records shall have been maintained.

9.1.3 Marking of ceramic components

In addition to the requirements of 9.1, a unique serial number shall be applied to each component of the joint prosthesis, which shall relate to the type of material and details of manufacture.

9.2 Marking of unit packages or outer containers

Unit packages or containers shall be marked in accordance with the requirements of ISO 6018. In addition, the package or container shall be marked with the markings of the different components it contains (see 9.1) and, if appropriate, the marking required by clause 7. If appropriate, instructions for sterilization shall be included.

Annex

Guidance on the use of joint prostheses

(This annex does not form part of the standard.)

A.1 If the unit container of a component made of plastics material is opened outside the control of the manufacturer and the component is not implanted at that time, the component should be discarded.

A.2 Ceramic components should not be sterilized by heat when fitted to the stem because the dissimilar coefficients of expansion of the ceramic material and the metal may introduce stresses in the ceramic component which can lead to cracking. Ceramic components sterilized separately by heat should be allowed to cool slowly in air to ambient temperature before fitting to a prosthesis which should also be at ambient temperature. Great care should be exercised when fitting the components together; hand pressure only should be used unless otherwise recommended by the manufacturer.

A.3 If a critical surface, for example a bearing surface, of any component is damaged, the component should not be implanted.

The insertion and removal of a prosthesis for the purposes of trial fitting at the time of the operation can damage the prothesis. For this reason, reduction tests have to be carried out using a test prosthesis, except in those cases where the prostheses are designed with protection for the bearing areas of the components. The use of a test prosthesis precludes the risk of contamination of components that might occur during trial fitting. It is important, once implantation has been completed, that no components are used again after their removal.

A.4 Manufacturers should not refurbish any returned components that have been implanted in a patient.

A.5 Any component removed from a patient or otherwise exposed to infection or body fluids should be sterilized prior to dispatch for examination other than by a microbiologist. The sterilization of metal components which do not incorporate plastics materials can be carried out using steam or dry heat. If these methods cannot be used, the components should be rendered as safe to handle as possible by subjecting them to a recognized disinfection or sterilization procedure. Components made of plastics materials and those incorporating plastics materials should be carefully and thoroughly washed and then disinfected by immersion in a suitable solution such as freshly prepared 2 % buffered glutaraldehyde solution for a period of not less than 3 h at room temperature.

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